CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: ~~Assistant~~ Commissioner for Patents, ~~Arlington, VA 22202~~, on the date appearing below.

ELI LILLY AND COMPANY ALEXANDRIA, VA 22313-1450

By Linda M. Dunbin Date October 19, 2005

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	C.M. Chang and H. Havel	)
Serial No.	:	10/055,509	)
Filed	:	January 23, 2002	) Group Art Unit: 1653
For	:	Stabilized Teriparatide Solutions	) Examiner: A. Gupta
Docket No.	:	X-10911 A	)

DECLARATION UNDER 37 C.F.R. 1.132

Assistant Commissioner for Patents
Arlington, VA 22202
Sir:

I, Daniel F. Lynch, declare that:

I hold the degrees of Bachelor of Science in Mechanical Engineering and Master of Business Administration.

I have been employed since 1980 by Eli Lilly and Company in the following capacities: Parenteral Engineer, Department Head Parenteral Operations, Manager Parenteral Validation, Development Projects Manager, and Director Parenteral Manufacturing Science and Technology.

I am the inventor or co-inventor of two United States patents.

I further declare that I have read the patent application identified above and make the following statements about its contents.

1. The application describes a freeze-dried PTH formulation in containers such as vials for subsequent reconstitution and use by a patient.

2. The application also describes a *liquid* injectable pharmaceutical formulation containing PTH, which does not undergo a step of freeze-drying prior to use by a patient.

3. The liquid formulation is described as "ready to administer." This phrase has a particular meaning in the art, namely that the formulation is ready to use in a patient without the need for additional processing steps such as freeze-drying and/or reconstitution. A liquid prepared by reconstituting a freeze-dried powder is not referred to as "ready to administer."

4. The application states that the liquid formulation is sterile. Sterility can be achieved by heat treatments, filtration, irradiation, or a combination of these processes. Protein and peptide components such as PTH, which are heat labile, are best sterilized by filtration. Once a formulation is sterilized it must be protected from the environment in order to maintain adequate sterility, as required by regulatory agencies. All steps subsequent to sterilization and filling a container, must assure adequate protection from the environment in order to avoid contamination and maintain sterility.

5. Sealing a pharmaceutical formulation in a vial or cartridge has long been standard practice in the industry, and is necessary to maintain sterility. For example, vials are typically sealed with elastomeric stoppers and held in place by aluminum caps. Thus, the containers described in this application *must be* sealed in order to maintain sterility and shelf-life of the formulation product, and to fulfill regulatory requirements.

6. I further state that sealing containers such as vials and cartridges has been standard practice in the pharmaceutical industry for many years. Processes for

sealing a container are well known to skilled artisans in the industry.

I further declare that all statements made herein of my own knowledge are true, that all statements made on information and belief are believed to be true, and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both (18 U.S.C. 1001), and may jeopardize the validity of the application or any patent issuing thereon.

Declarant's Name

9-20-2005

Date